

REMARKS

Claims 1-49 are all the claims pending in the application; claims 2-4, 12-15, 21-24 and 30-41 have been withdrawn from consideration; claims 1, 6-11, 16-20, 25-29 and 42-49 have been rejected; claim 5 has been allowed.

After entry of this amendment, claims 5-9, 11-24, 34 and 36-41 will be pending, and claims 1-4, 10, 25-33, 35 and 42-49 will be canceled.

The claims have been amended to recite the parental strain from which the enhanced bacterial strains are produced. Support for the amendment may be found in the specification, for example at page 4, lines 5-12 and page 5, lines 7-9, where enhanced *Actinosynnema* and *Actinosynnema pretiosum* strains producing increased levels of ansamitocins, such as maytansinoids, and derived from the *Actinosynnema* strain ATCC 31565, are discussed.

No new matter has been added. Entry of this amendment is respectfully requested.

I. Formal Matters

While the Examiner lists claim 11 as being withdrawn from consideration on the Office Action Summary sheet (as being directed to the non-elected invention), as this claim is to a microorganism (the elected invention) and not a method of using the microorganism (the non-elected invention), Applicants believe and request that it should properly be included in the group of claims under consideration and not withdrawn.

II. Rejection Under 35 U.S.C. §112

A. At paragraph 4A of the Office Action, claims 1, 6-10, 16-20, 25-29 and 42-49 are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

The Examiner states that the rejected claims recite subject matter which is not described in the specification in such a way as to enabled the skilled artisan to make and use the invention with respect to the microorganisms per se.

The Examiner states that specific mutant strains of a microorganism are required to practice the invention recited in the claims (i.e., those microorganisms having the biological characteristics (increased ansamitocin production) of the bacterium having ATCC accession number PTA-3921). Furthermore, as a required element of the invention, the strains must either be known and readily available to the public, or obtainable by a repeatable method set forth in the specification. Alternatively, the deposit of a reasonable number of mutant strains with an approved depository may be made.

The Examiner asserts that because the specification allegedly does not provide a repeatable method for obtaining the mutant strains, and that the strains do not appear to be readily available, deposit of a reasonable number of strains is required to meet the enablement requirements of 35 U.S.C. §112.

In response, Applicants first note that the claims have been amended such that claims 1, 10, 25-29 and 42-49 have been canceled, and thus the rejection is moot as to these claims.

Of the remaining claims included in this rejection (claims 6-9 and 16-20), Applicants note that the claims have been amended such that they now encompass a small number of bacteria (*Actinosynnema* and *Actinosynnema pretiosum* strains), that are derived from one parental bacterial strain (*Actinosynnema pretiosum* strain ATCC 31565) and that produce a defined amount (between about 1.2 fold and about 10 fold more) of a particular group of proteins (ansamitocins).

Applicants further note that the specification provides a repeatable method for obtaining the bacterial strains recited in the amended claims (pages 10-12 and 17-19). In support of the teachings of the specification, Applicants include herewith an executed Declaration Under 37 C.F.R. §1.132 by one of the inventors (Dr. Byng), who is also an expert in the field of mutational improvements of microbial strains.

In the Declaration, Dr. Byng discusses the reproducible methods for producing the mutant strains and for testing the strains for the desired characteristics that are given in the specification. He also discusses how practicing the method is well within the purview of the skilled artisan, and that the skilled artisan would readily expect that mutant strains producing increased levels of ansamitocin could be easily isolated.

In view of the disclosure in the application of an enhanced *Actinosynnema* strain that produces higher levels of ansamitocin (recited in claim 5) and a method for producing such an enhanced strain, and the Declaration asserting that the skilled artisan could easily follow the procedures set forth in the specification to produce additional strains with increased ansamitocin production, Applicants respectfully assert that the claims, as amended, are enabled. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

B. At paragraph 4B of the Office Action, claims 1, 6-10, 16-20, 25-29 and 42-49 are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

The Examiner states that the specification does not provide sufficient enablement to make and use the invention as broadly claimed, absent additional deposits or supporting evidence pertaining to guidance as to the distinguishing characteristics for the claimed subject matter.

In response, Applicants first note that the claims have been amended such that claims 1, 10, 25-29 and 42-49 have been canceled, and thus the rejection is moot as to these claims.

Of the remaining claims included in this rejection (claims 6-9 and 16-20), Applicants note that the claims have been amended such that they now encompass a small number of bacteria (*Actinosynnema* and *Actinosynnema pretiosum* strains), that are derived from one parental bacterial strain (*Actinosynnema pretiosum* strain ATCC 31565) and that produce a defined amount (between about 1.2 fold and about 10 fold more) of a particular group of proteins (ansamitocins).

As discussed above, the application applications discloses an enhanced *Actinosynnema* strain that produces higher levels of ansamitocin (recited in claim 5) and a method for producing such enhanced strains. As also discussed above, included herewith is the Declaration of Dr. Byng, wherein it is stated that the skilled artisan could easily follow the procedures set forth in the specification to produce additional strains with increased ansamitocin production. In view thereof, Applicants respectfully assert that the claims, as amended, are enabled. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

C. In the third full paragraph on page 6 of the Office Action, claims 1, 6-10, 16-20, 25-29 and 42-49 are rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description support in the specification as filed.

The Examiner states that the broad generic claim lacks sufficient description to inform a skilled artisan that Applicants were in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described.

The Examiner explains that additional disclosure, such as the effect the mutagen has on a particular component of the metabolic pathway leading to increased ansamitocin production or structural characteristics of the members of the genus of bacteria being claimed, is necessary.

In response, Applicants first note that the claims have been amended such that claims 1, 10, 25-29 and 42-49 have been canceled, and thus the rejection is moot as to these claims.

Of the remaining claims included in this rejection (claims 6-9 and 16-20), Applicants note that the claims have been amended such that they now encompass a small number of bacteria (*Actinosynnema* and *Actinosynnema pretiosum* strains), that are derived from one parental bacterial strain (*Actinosynnema pretiosum* strain ATCC 31565) and that produce a defined amount (between about 1.2 fold and about 10 fold more) of a particular group of proteins (ansamitocins).

Applicants respectfully assert that the scope of the invention, as recited in the amended claims, is adequately described in the specification as filed. Furthermore, the skilled artisan would understand the scope of the invention based on the limited number of species encompassed within the amended claims, and the recited functional characteristics of the members of the genus (increased ansamitocin production). Applicants note that only three species have been classified within the genus *Actinosynnema*.

In view of these comments and the amendments to the claims, Applicants respectfully request reconsideration and withdrawal of the rejection.

III. Rejection Under 35 U.S.C. §102

At paragraph 5 of the Office Action, claim 1 is rejected under 35 U.S.C. §102, as being anticipated by Hasegawa et al. (U.S. Patent No. 4,331,598) for ATCC 31565 or Hasegawa et al. (U.S. Patent No. 4,450,234) for ATCC 15005.

In response, Applicants note that claim 1 has been canceled, thus making this rejection moot. In view of the cancellation of claim 1, Applicants respectfully request reconsideration and withdrawal of this rejection.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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